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PHARMACEUTICAL
INSTITUTE

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WE ARE COMMITTED TO
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SCIENTIFIC RESEARCH,
DEVELOPMENT AND
RESOURCES TO ENCOURAGE
SAFE AND MORAL MEDICINES
AND THERAPEUTICS.

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Autism Disorder Changepoints
and Environmental Triggers

Vaccine Manufacturing Contaminants You Have Not Been Told About and Autism

Theresa Deisher, Ph.D.
*Sound Choice Pharmaceutical Institute
Seattle, WA*

Autism One 2013 Chicago

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Autism Disorder Changepoints
and Environmental Triggers

Disclosures:
Stanford University, Ph.D. in Molecular and Cellular Physiology
Commercial Positions
Genentech
Repligen
ZymoGenetics
Immunex
Amgen
AVM Biotechnology : program to develop and
commercialize vaccines to replace those manufactured
using aborted fetal cell lines

23 Issued Patents; none in the vaccine area
3 discoveries in clinical trials ; none in the vaccine area

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Autism Disorder Changepoints
and Environmental Triggers

Autism Disorder Changepoints (AD CPs)

Vaccine Manufacturing and Contaminants
Vaccine Events Associated with AD CPs
Biological Effects of Vaccine Contaminants
Summary

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Autism Disorder Changepoints
and Environmental Triggers

What is a Changepoint?

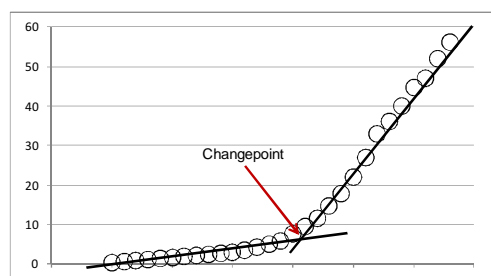
Identification of the point in a time series at
which some change occurs

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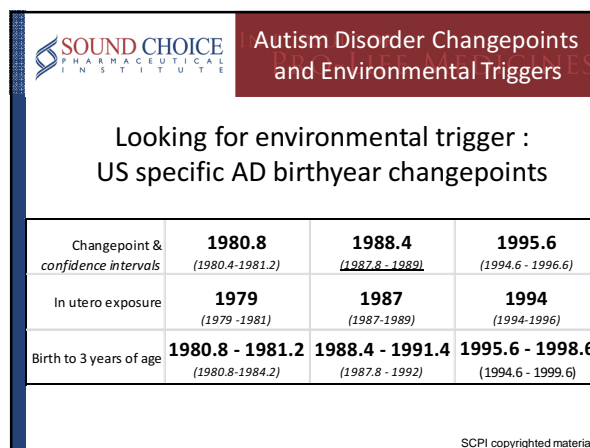
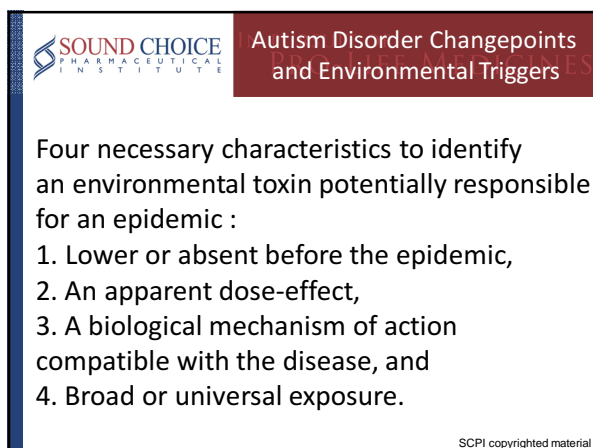
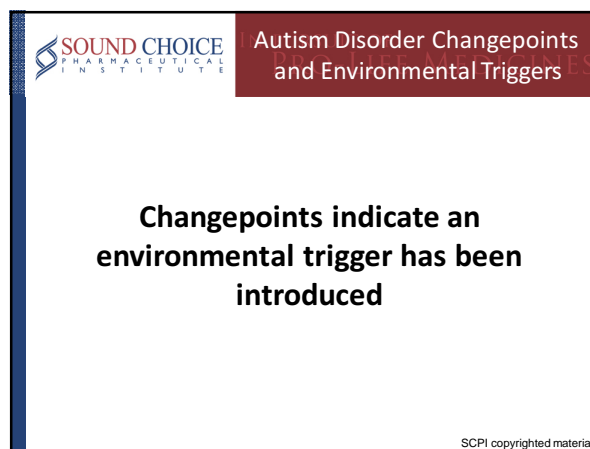
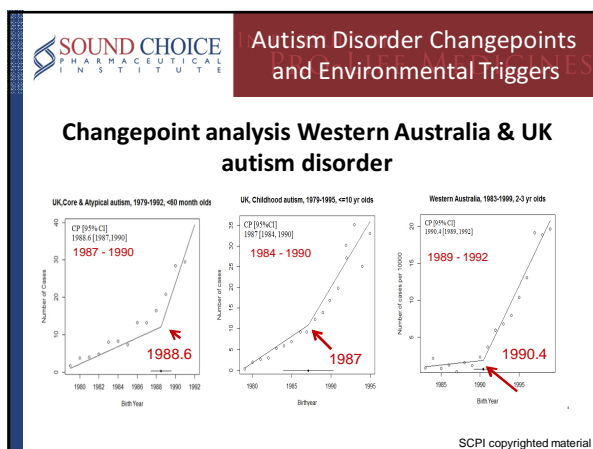
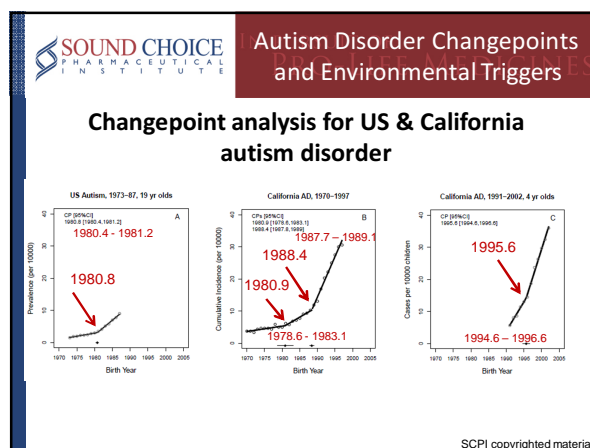
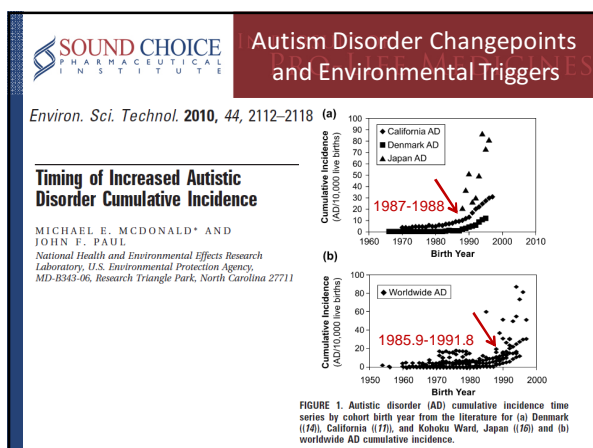
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Autism Disorder Changepoints
and Environmental Triggers

What is a Changepoint?



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**Autism Disorder Changepoints
and Environmental Triggers**

Looking for environmental trigger :
Commonwealth AD birthyear changepoints

	UK	West Aus
Changepoint & confidence intervals	1987 (1984 - 1990)	1990.4 (1989 - 1992)
In utero exposure	1986 (1983-1989)	1989 (1988-1991)
Birth to 3 years of age	1987 - 1990 (1984 - 1993)	1990.4 - 1993.4 (1989 - 1995)

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**Autism Disorder Changepoints
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**What are we really giving
our children in vaccines?**



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Each vial contains DNA and
debris from the manufacturing cell

**Residual Contaminants from
Manufacturing Cell**

DNA and cellular debris



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**Package inserts do not fully
disclose these contaminants**

MERCK & CO., INC.
Whitehouse Station, NJ 08889, USA

VARIVAX®
Varicella Virus Vaccine Live

The package insert **does** disclose the contaminants:
Each 0.5 mL dose contains the following: a minimum of 1350 PFU (plaque forming units) of Oka/Merck varicella virus when reconstituted and stored at room temperature for 30 minutes, approximately 25 mg of sucrose, 12.5 mg hydrolyzed gelatin, 3.2 mg sodium chloride, 0.5 mg monosodium L-glutamate, 0.45 mg of sodium phosphate dibasic, 0.08 mg of potassium phosphate monobasic, 0.08 mg of potassium chloride; **residual components of MRC-5 cells including DNA and protein;** and trace quantities of sodium phosphatemonobasic, EDTA, neomycin, and fetal bovine serum. The product contains no preservative.

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Varivax contains about twice
the contaminant as active ingredient

**Varivax (chickenpox) contains
over 2 ugs of contaminating
human fetal DNA**

SUMMARY FOR BASIS OF APPROVAL

Reference Number: 93-0395
Merck and Co.
Varicella Virus Vaccine Live
VARIVAX®

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Not all package inserts disclose these contaminants at all

MERCK & CO., INC.
Whitehouse Station, NJ 08889, USA

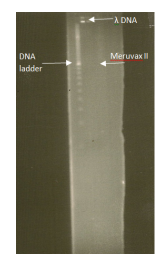
M-M-R® II
(MEASLES, MUMPS, and RUBELLA VIRUS VACCINE LIVE)

The package insert **does not** disclose the contaminants:
Each 0.5 mL dose contains not less than 1,000 TCID₅₀ of measles virus; 12,500 TCID₅₀ of mumps virus; and 1,000 TCID₅₀ of rubella virus. Each dose of the vaccine is calculated to contain sorbitol (14.5 mg), sodium phosphate, sucrose (1.9 mg), sodium chloride, hydrolyzed gelatin (14.5 mg), recombinant human albumin (≤0.3 mg), fetal bovine serum (<1 ppm), other buffer and media ingredients and approximately 25 mcg of neomycin. The product contains no preservative.

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IN PURSUIT OF PRO-LIFE MEDICINES

The Rubella component of the MMR II contributes over 150 ngs of human fetal DNA fragments at the perfect size for insertional mutagenesis to occur.



Human ddDNA (qPCR array) and ssDNA (oligo array) levels in Harris (Hep-2) and Meruvax II (Rubella) and residual size (SYBR GOLD).

Meruvax II contains >140ng/vial ssDNA and >30ng/vial ddDNA with average length of 215 bp. Harris contains >270ng/vial ssDNA and >30ng/vial ddDNA.

	ssDNA (ng/vial)	ddDNA (ng/vial)	size (bp)
Rubella (Meruvax II)	142.05	35.00	215.00
Hepatitis A (Harris)	276.00	35.74	>48.5K

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Autism Disorder Changepoints and Environmental Triggers

Vaccines manufactured using the WI-38 cell line are also contaminated with a retrovirus (fragment of HERV)

Vaccine	Disease	Date US Approved	Year used	Age Group(s)	Fetal Cell line(s)
Meruvax II	Rubella	01/1979	1979	> 12 months	RA27/3/ WI-38
MMR II	Mumps Measles Rubella	01/1979	1979	>12 months	RA27/3/ WI-38
Varivax	Chickenpox	03/17/1995	1995	>12 months	WI-38 /MRC-5

JOURNAL OF VIROLOGY, June 2010, p. 6033-6040

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Commonwealth fetal vaccination summary

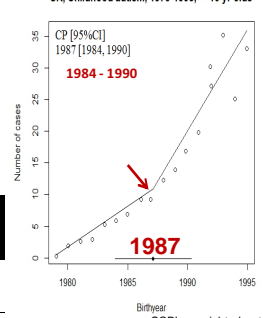
Vaccine	Disease	Date Approved	Country	Age Group(s)	Fetal Cell line(s)
MMR (3 versions)	Mumps Measles Rubella	10/1988	UK	>12 months	RA27/3/WI-38/MRC-5
MMR II	Mumps Measles Rubella	1989	Australia	>12 months	RA27/3/WI-38
Varivax	Chickenpox	1999	Australia	>12 months	WI-38/MRC-5

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UK fetal Vaccines & AD CP

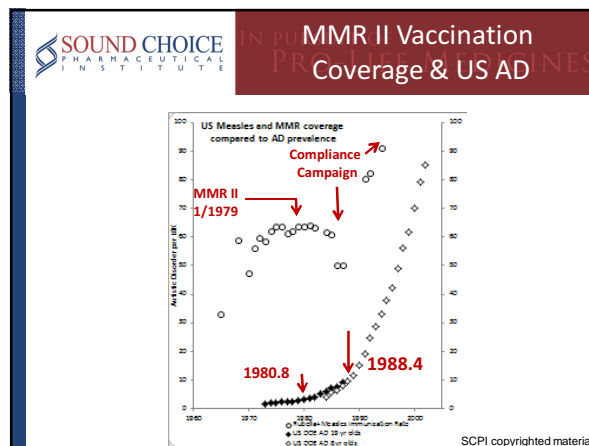
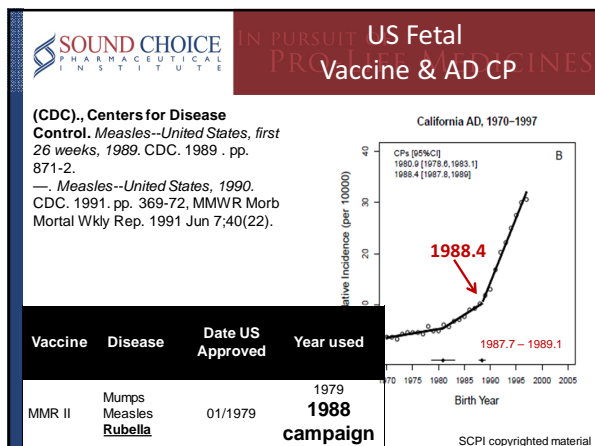
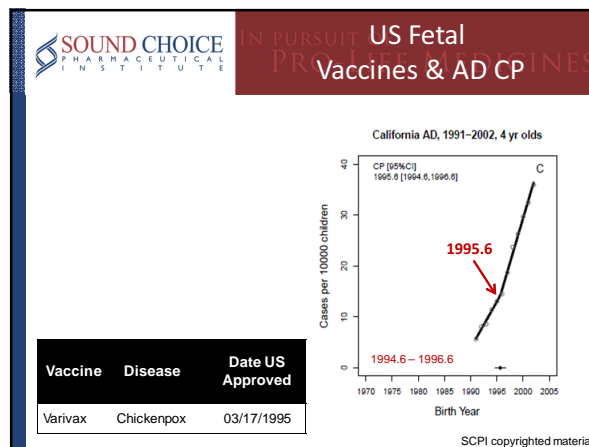
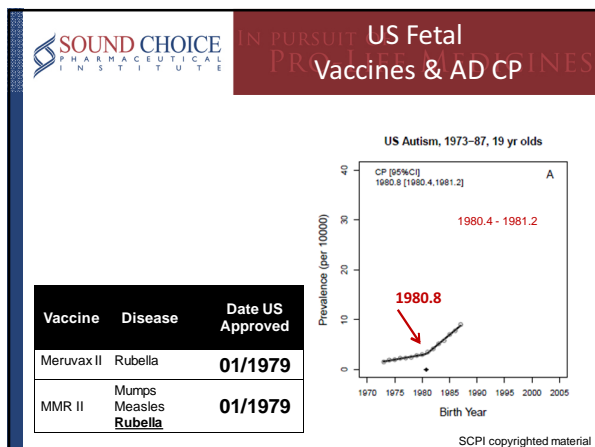
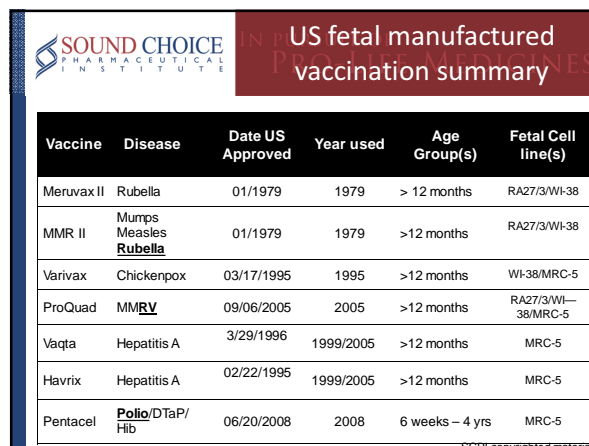
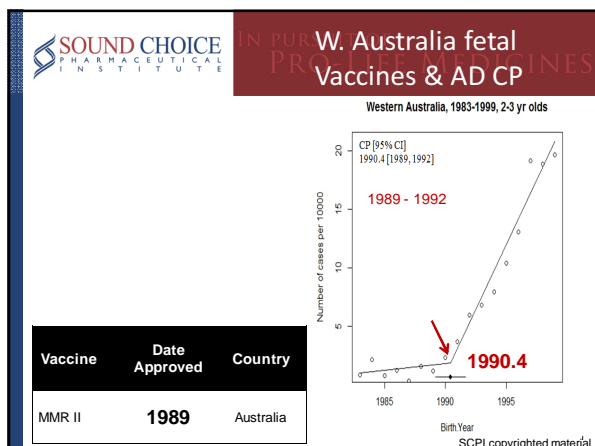
UK, Childhood autism, 1979-1995, <10 yr olds

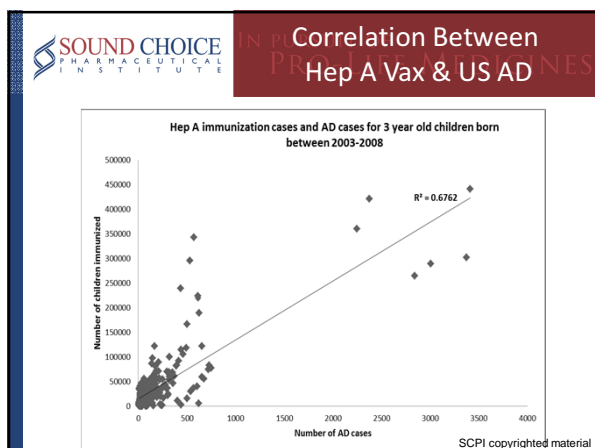
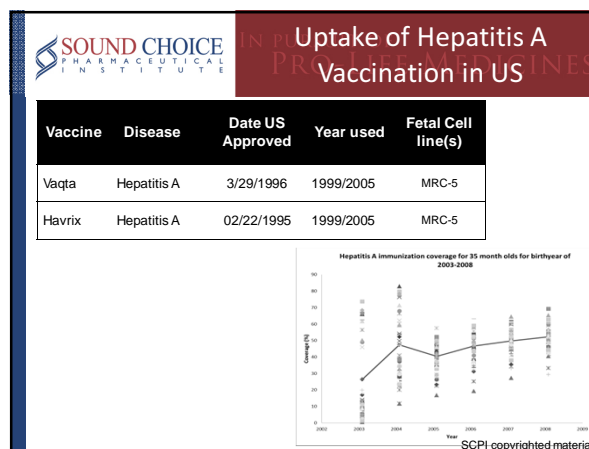
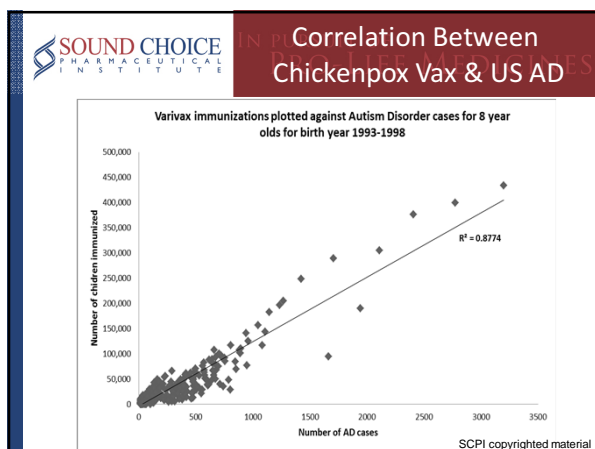
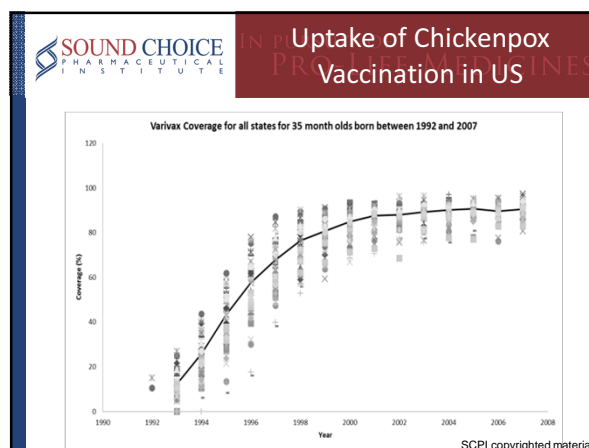
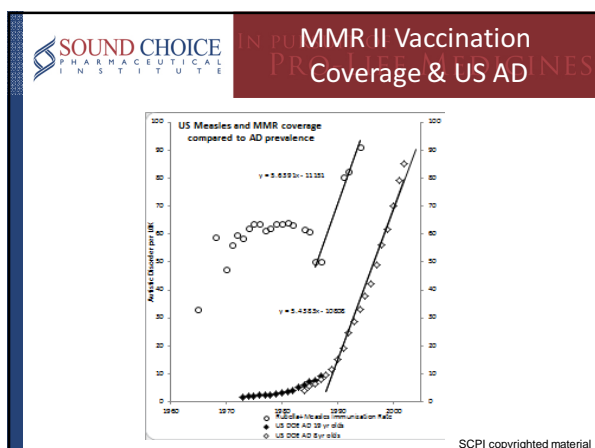


CP [95%CI]
1987 [1984, 1990]
1984 - 1990

Vaccine	Date Approved	Country
MMR (3 versions)	10/1988	UK

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Vaccine Events Associated with AD CPs - summary

1. Autism disorder changepoints in the US, UK and Western Australia are associated with the introduction of vaccines manufactured in, and contaminated with, human fetal cell lines.
2. Yearly increases in US AD diagnosis are significantly related to increases in vaccine coverage of Varivax (chickenpox) and Hepatitis A.
3. AD increases also follow MMR II coverage.

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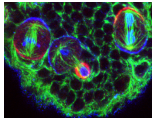
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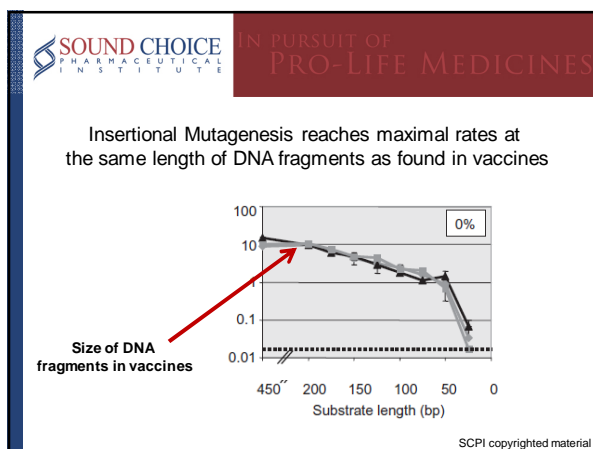
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**Potential responses to
contaminants from human cell lines**

Auto-immune response
Integration of residual DNA into genome
insertional mutagenesis

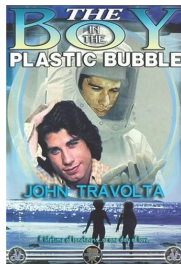


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For gene therapy, 9 boys were given
essentially the same ingredients as
the contaminants in vaccines:

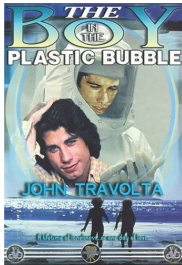
- Human DNA fragment
1114 base pairs long
- Fragment of the MMLV
retrovirus

J Clinical Investigation 2008 v118 Howe *et. al.*

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Outcome : cancer in 4 of 9* boys



Inappropriate gene insertion
into LMO2

overexpression
hematopoietic development accelerated

Additional somatic mutations
in leukemic cells

J Clinical Investigation 2008 v118 Howe *et. al.*

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 **Summary** IN PURSUIT OF PRO-LIFE MEDICINES

Autism Disorder changepoints

- point to environmental trigger(s)
- correspond to switch from animal to human fetal vax manufacturing.

Fetal DNA contaminants can cause de novo mutations in the genome &/or auto-immune disease.


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 **Summary** IN PURSUIT OF PRO-LIFE MEDICINES

Four necessary characteristics to identify an environmental toxin responsible for an epidemic :

1. Lower or absent before the epidemic,
Fetal cell based manufacturing
2. An apparent dose-effect,
MMRII, Varivax, Hepatitis A, Pentacel
3. A biological mechanism of action compatible with the disease,
Insertional mutagenesis & Autoimmunity
4. Broad or universal exposure,
Universal vaccination programs.

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 **Summary** IN PURSUIT OF PRO-LIFE MEDICINES

Public data justifies retrospective studies of the Vaccine Safety Datalink to determine the relative risk of autism disorder with use of human fetal manufactured vaccines.

At a minimum, parents should be informed.

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